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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,271	09/10/2001	George M Yousef	MTS3USA	2550
270	7590	11/02/2004	EXAMINER	
HOWSON AND HOWSON ONE SPRING HOUSE CORPORATION CENTER BOX 457 321 NORRISTOWN ROAD SPRING HOUSE, PA 19477			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 11/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,271

Applicant(s)

YOUSEF ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33 and 47-60 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 33 and 47-53 is/are allowed.
6) ☒ Claim(s) 54-60 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 10 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 33 and 47-60 are pending in the application.

This Office Action is in response to the Amendment filed on 8/17/04.

Response to Amendment

The objection to claim 52 has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claim 49 under 35 U.S.C.101 has been withdrawn in light of Applicant's amendment of the claim.

The rejection of claims 33, 47, 48 and 50 under 35 U.S.C. 112 1st paragraph (scope of enablement) has been withdrawn in light of Applicant's amendment of the claims.

Claim 54 and newly added claims 55 and 56 stand rejected under 35 U.S.C.112 1st paragraph (new matter) for reasons set forth of the record mailed on 5/17/04 and further

Newly added claims 57-60 are rejected under 35 U.S.C.112 1st paragraph for reasons set forth of the record mailed on 5/17/04 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 54 and newly added claims 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that one of ordinary skill in the art would readily recognize the recited nucleic acid sequence based on the teaching of specification, Figure 7 and SEQ ID NO:13. Applicants assert that the recited fragments represent either exon or intron of the KLK-L2 gene, and are readily identified by Figure 7. Applicants thus conclude that they do not constitute new matter.

These arguments have been fully considered but deemed unpersuasive. As discussed in previous office action, the MPEP states "New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method." See MPEP § 608.04 to § 608.04(c). The specification does not disclose these specific recited fragments. SEQ ID NO:13 is the entire genomic sequence of KLK-L2 gene, which does not list these specific fragments. Figure 7 illustrates the exon intron boundary without indicate these specific fragments as well. The Figure 7 with labeled fragments provided in exhibit A is not the original drawing provided with the specification. The original Figure 7 (and the description provided in the specification) entered on 9/10/01 does not have list any fragments. Therefore, the specification does not provide sufficient support for the recited fragments. Thus, the new matter rejection is maintained.

Claims 55 and 56 are rejected for same reason as discussed above.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 57 is rejected for same reason as discussed in previous office action (5/17/04) as applied to original claim 33 (see page 3, last paragraph through page 5). Briefly, the specification discloses that SEQ ID NO:13 is a genomic DNA sequence encoding KLK-L2 protein, and it is about 11.5kb in length. This gene encodes a polypeptide that consists 293 amino acid. However, the specification does not disclose a RNA sequence represented by the sequence of SEQ ID NO:13, in which the T is replaced with U. Further, the specification fails to teach a method to make the RNA represented by SEQ ID NO:13, or how to use such RNA molecule. The prior art teaches that a genomic sequence encoding a protein comprises 5' or 3' regulatory region, introns and exons. Messenger RNA is transcribed from only exons of said genomic sequence, which skips the sequences from 5' or 3' regulatory region and introns. There is no RNA 100% complementary to a gene (genomic DNA sequence comprises 5' or 3' regulatory region, introns and exons). Therefore, one skilled in the art would have to rely on the teaching of the specification to make and use the invention as claimed. The specification only

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teaches a nucleic acid sequence represented by SEQ ID NO:13, in which T can also be U. The specification fails to teach how to make and use such RNA molecules. Without such information, one skilled in the art would have to engage in undue experimentation to make and use the claimed invention.

Applicants' argument that generating RNA from the disclosed DNA is common knowledge is unpersuasive. Although replacing T to U may be achievable, the specification fails to teach how to use such RNA spanning both intron and exon of the genomic sequence that encodes KLK-L2. Therefore, the claimed invention is not enabled by the instant specification.

Claims 58-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the

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claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims are drawn to an isolated nucleic acid molecules which hybridize to SEQ ID NO:13 under stringent condition. The claims encompass potentially a large genus of nucleic acid molecules of various sizes and structures. The specification only discloses one KLK-L2 protein having the genomic sequence of SEQ ID NO:13. The specification fails to disclose any other nucleic acids of various sizes that hybridize to SEQ ID NO:13 encode the KLK-L2 protein which possesses serine protease function. As such, the structural functional relationship between the claimed nucleic acid molecule and its function as a serine protease is missing. Therefore, the written description requirement is not met.

Conclusion

Claims 33, 47-53 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

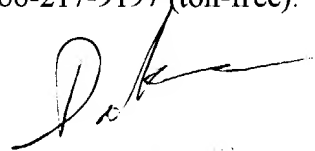
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Celine Qian, Ph.D.